REMARKS

The Examiner is thanked for withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Claims 3-15 and 17 have been amended to replace "A" with "The", to place the claims in proper form.

Claim 14 has been amended to delete "from about 10 to about 30 % by weight of a fat soluble vitamin and," which is redundant to the same limitation in claim 1.

Claims 2, 16, and 18-27 have been cancelled without prejudice.

Claims 28-35 have been added.

Support for claim 28 is found in the specification at, for example, Page 6, line 25 to Page 7, line 23.

Support for claim 29 is found in the specification at, for example, Page 2, lines 14-20, page 3, lines 11-21, page 6, lines 19-31, page 20, line 15 to page 21, line 5, page 23, lines 19-22, and Example 1; and original claims 1 and 22. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973).

Support for claim 30 is found in the specification at, for example, Page 20, lines 22-24, and page 24, lines 21-22.

Support for claim 31 is found in the specification at, for example, Page 20, lines 26-27, and Example 1; and original claim 23. (Id.)

Support for claim 32 is found in the specification at, for example, Page 20, line 28 to Page 21, line 2, and page 21, line 12 to Page 22, line 7.

Support for claim 33 is found in the specification at, for example, Page 24, lines 17-20.

Support for claim 34 is found in the specification at, for example, Page 20, line 28 to Page 21, line 2; and original claim 24.

Support for claim 35 is found in the specification at, for example, Page 6, line 25 to Page 7, line 23.

No new matter has been added.

We note that the presentation of claims 29-35, in product-by-process format, underscores the importance and uniqueness of the process used to make the claimed powder composition.

Interview Summary

The Examiner is thanked for the courtesies extended during the telephonic Interview of August 5, 2009, in which the inventor, Dr. Bruno Leuenberger, participated. We also thank the Examiner for issuance of the Examiner's Interview Summary on August 10, 2009 (Paper No. 20090805). During the Interview, it was discussed that based on the cited U.S. Patent No. 5,968,251 to Auweter ("Auweter"), one skilled in the art would not expect success in achieving the claimed powder composition in which solid droplets of a fat-soluble vitamin having an average diameter of about 80 to about 120 nm are present, and in which the powder composition achieves the inherent advantages of optical clarity and appearing transparent and/or translucent in solution upon addition to a clear liquid. The disclosure of Auweter does not suggest formulations having the claimed droplet size. Nor does Auweter suggest

formulations which have optical clarity and which appear transparent and/or translucent in an otherwise clear solution.

It was also discussed that the process of Auweter differs from the disclosed process used to prepare the claimed powder composition. The process of Auweter was likened to the process of EP 937412 to Stein ("Stein"), also cited by the Examiner. The Declaration of Mr. Hermann Stein Under 37 C.F.R. § 1.132, which is of record, was also discussed. During the Interview, it was suggested that a Declaration under 37 CFR § 1.132 of Bruno Leuenberger be submitted in connection with the response to the Final Action. The Examiner indicated that she would consider such a Declaration if submitted. Accordingly, the Declaration of Bruno Leuenberger, Ph.D., Under 37 CFR § 1.132 ("the Leuenberger Declaration") is submitted herewith.

Obviousness Rejections

A. Claims 1, 3-14 and 17: Auweter Alone or In View of Stein

Claims 1, 3-14 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,968,251 to Auweter et al. ("Auweter") alone or Auweter in view of EP 937412 to Stein et al. ("Stein"). (Paper No. 20090330 at 2.)

Although both Auweter and Stein were previously addressed on the record, we provide a summary of each for the Examiner's convenience.

Auweter discloses that carotenoids are "entirely insoluble" in water. (Col. 1, lines 42-51.) Auweter set out to prepare coloring compositions using carotenoids, and sought to overcome the "poor coloring results" that had previously been obtained due to the insolubility of carotenoids. (Id.)

Auweter further discloses "coldwater-dispersible dry powders which contain carotenoids and are obtainable [by the process disclosed] and which have different color effects depending on the production variant." (Col. 1, lines 26-29.) Auweter also discloses that the "[c]arotenoid preparations in the form of coldwater-dispersible powders are produced by[:]

> a) preparing a molecular-disperse solution of a carotenoid, with or without an emulsifier and/or an edible oil, in a volatile, water-miscible, organic solvent at elevated temperature and adding therein an aqueous solution of a protective colloid, whereupon the hydrophilic solvent component is transferred into the aqueous phase, and the hydrophobic phase of the carotenoid results as [the] nanodisperse phase,
>
> b) heating the resulting hydrosol at from 40° C. to 90° C., with or without cooling of the hydrosol to from 0° C. to 30° C. beforehand, and
>
> c) removing the solvent and the water from the heated hydrosol, and converting it into a water-dispersible dry powder. (Abstract.)

Auweter discloses that the molecular disperse solution according to process step a) can be carried out "under atmospheric or superatmospheric pressure." (Col. 2, lines 47-54.) According to Auweter, "[s]uperatmospheric pressure, *e.g.* in the range from 20 bar to 80 bar, preferably 30 to 60 bar, may be advantageous for rapid preparation of the molecular-disperse solution." (Col. 2, lines 59-62.) Auweter also discloses that in example 1, "[t]he ... process took place under 30 bar..." (Col. 6, line 48-49.)

"Examples of protective colloids which are used" in accordance with Auweter are said to be "gelatin, fish gelatin, starch, dextrin, vegetable proteins, pectin, gum arabic, casein, caseinate or mixtures thereof." (Col. 4, lines 40-42.) Auweter

discloses, however, that "it is also possible to employ polyvinyl alcohol, polyvinylpyrrolidone, methylcellulose, carboxymethylcellulose, hydroxypropylcellulose and alginates." (Col. 4, lines 43-46.)

Auweter also discloses that "[t]he result is a dry powder which, on use of a water-soluble colloid, can be dissolved again in water to obtain a uniform dispersion of the active substance with particle sizes in the range below 1 μm. The active substance hydrosol obtained in this way proves to be extremely stable..., despite the fine particles." (Col. 5, lines 28-34.) Auweter further discloses that "[t]he preparations according to the invention are, by reason of their good coldwater dispersibility, outstandingly suitable as coloring agents ..." (Col. 5, lines 35-37.) In addition, Auweter discloses that one of the process variants results in "the precipitated active substance particles after heating [being] essentially spherical with a diameter of, typically, 200 nm." (Col. 3, lines 52-57.) There is no disclosure in Auweter of any particle size of precipitated active substance that does not have at least a 200 nm diameter in one direction.

Auweter further discloses that Example 1, which includes β-carotene, dl-α-tocopherol, and gelatin, "[resulted] in a colloid-disperse β-carotene dispersion with a yellow hue. Spray drying the dispersion resulted in a free-flowing dry powder which forms a clear yellow dispersion in water." (Col. 6, lines 47-48 and 52-58.) In Example 2, it is disclosed that "β-[c]arotene was precipitated in colloid-disperse form as described in Example 1." (Col. 6, lines 61-62.) Auweter further discloses that upon processing, Example 2 "[resulted] in a colloid-disperse β-carotene dispersion with an

orange hue. Spray drying of the dispersion resulted in a free-flowing dry powder which forms a clear orange dispersion in water." (Col. 6, line 61 to Col. 7, line 2.)

Stein discloses "a continuous process for the preparation of a pulverous carotenoid, retinoid or natural colourant preparation, wherein the active ingredient is finely divided ...." (Abstract). The process includes the steps of:

> a) forming a suspension of the active ingredient in a water-immiscible organic solvent optionally containing an antioxidant and/or an oil,
> b) feeding the suspension of step a) to a heat exchanger and heating said suspension to 100-250°C, whereby the residence time in the heat exchanger is less than 5 sec,
> c) rapidly mixing the solution of step b) at a temperature in the range of 20-100°C with an aqueous solution of a swellable colloid optionally containing a stabilizer,
> d) removing the organic solvent and
> e) converting the dispersion of step d) into a pulverous preparation. (Col. 2, lines 3-16.)

The "finely divided" starting material is said to be of "a particle size of less than 1.5 micron, preferably less than 1 micron, more preferably less than 0.4 micron." (Col. 2, lines 18-21.) Stein further discloses that the "swellable colloid" can include gelatin, carbohydrates, dextrin, pectin, gum arabic, octenylbutanedioate amylodextrin, milk proteins, and vegetable protein, or mixtures thereof. (Col. 3, lines 2-8.) Stein also discloses that powders formed from the compositions are soluble in cold water and provide coloration. (See Examples 1-5.)

We also refer to the Declaration of Mr. Hermann Stein Under 37 C.F.R. § 1.132 dated March 16, 2005 ("the Stein Declaration"), which is of record. The Stein Declaration was filed with the Submission Under 37 C.F.R. § 1.114; Response to Final Office Action, on March 24, 2005 (which was date stamped as received in the U.S. Patent and Trademark Office on March 28, 2005). It is noted that the Declarant of the

Stein Declaration, Mr. Hermann Stein, is the same Hermann Stein who is an inventor of the Stein document cited by the Examiner. A copy of the Stein Declaration is attached to the Leuenberger Declaration as Exhibit C.

In making the rejection, the Examiner asserted that "Auweter teaches cold water dispersible powders comprising fat soluble vitamins such as carotenoids prepared by the method described in [the] abstract and col. 2, L 27-46. For the protective colloids, Auweter teaches the claimed proteins such as fish gelatin, vegetable proteins, and also gum such as gum arabic (col. 4, L 40-53). Auweter teaches a 0.5-20% carotenoids and 10-50% by weight of a protective colloid (col. 4, L 53-59)." (Paper No. 20090330 at 2-3.) The Examiner also asserted that "Auweter teaches particles of 200 nm size (col. 3, L 51-56)." (Id. at 3.)

Regarding claims 10 and 11, the Examiner acknowledged that "Auweter teaches carotenoids [sic] esters and not the claimed vitamins." (Id.) The Examiner also acknowledged that "Auweter teaches the carotenoids [sic] powders for food compositions but not tablet preparations." (Id.)

The Examiner concluded, however, that "preparing an appropriate form of the composition such as powder or solid tablet or liquid depending on the food preparation would have been within the scope of a skilled artisan." (Id.)

In addition, the Examiner acknowledged that "Auweter does not exemplify any compositions with the claimed gums or proteins." (Id.)

Regarding Stein, the Examiner asserted that "EP '412 teaches finely divided pulverous carotenoids [sic] preparations formed by suspending the active ingredient in an organic solvent, feeding the suspension to a heat exchanger, [and]

rapidly mixing with a swellable colloid. EP teaches the particle size such as 213 nm, 225 nm or 400 nm. Among the colloids, EP teaches gelatin, starch, gums, pectin[,] etc[.] (col. 3, L 1-7)." (Id.)

The Examiner concluded that "[i]t would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the powders of Auweter by incorporating colloids such as polysaccharide gums or proteins such as those taught by Auweter or EP because both references are directed to preparing the claimed powders and further EP suggests colloids such as gelatin and gums as effective in preparing vitamin powder preparations. Further, Auweter suggests preparing the powders with or without an emulsifier and thus meet the claimed matrix claim limitations. Further, EP suggests including carotenoids as well as tocopherol (019) and also suggests particles of less than 400 nm (0009). Accordingly, absent any unexpected advantage, it would have been within the scope of a skilled artisan to prepare vitamin powder preparations of Auweter with the proteins or gums of either reference with the desired particle sizes." (Id. at 3-4.)

It is well settled the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and

modify the document(s) relied on by the Examiner as evidence of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731-32 (2007) (the obviousness "***analysis should be made explicit***" and the teaching-suggestion-motivation test is "***a helpful insight***" for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to modify document(s) must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion test "***must be based on objective evidence <u>of record</u>***." *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (emphasis added). *See also Examination Guidelines for Determining Obviousness*, 72 Fed. Reg. 57526, 57528 (October 10, 2007) ("The key to supporting any rejection under 35 USC § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.").

Respectfully, we submit that the rejection is devoid of a proper § 103 analysis in support of the proposed modification. All that is there are conclusory statements such as the assertion that "[i]t would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the powders of Auweter by incorporating colloids such as polysaccharide gums or proteins such as those taught by Auweter or EP because both references are directed to preparing the claimed powders and further EP suggests colloids such as gelatin and gums as effective in preparing vitamin powder preparations. " (Paper No. 20090330 at 3.)

Here, what the rejection should have done, but did not, was to explain on the record ***why*** one skilled in this art would modify the disclosures of Auweter and Stein in the manner proposed by the Examiner, to arrive at the claimed powder composition.

As is well settled, an Examiner cannot establish obviousness by locating documents which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. *Takeda Chem. Indus., Ltd v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. June 28, 2007) (citing *KSR*) (indicating that "it remains necessary to identify ***some reason*** that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound") (emphasis added); *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). But this is precisely what the Examiner has done here. Thus, the rejection is legally deficient and should be withdrawn for this reason alone.

Beyond looking at the cited documents to determine if any of them suggests doing what the inventors have done, one must also consider if the art provides the required expectation of succeeding in that endeavor. See *In re Dow Chem. Co. v. American Cyanamid Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). "Obviousness does not require absolute predictability, but a reasonable expectation of success is necessary." *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976). Furthermore, the U.S. Patent and Trademark Office Examination Guidelines at page 57527 provide the following guidance to Examiners: "In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge". However, no such motivation or expectation of success can be found in the cited documents.

Arguments on the record concerning each of Auweter and Stein are incorporated herein.

As evidence of the deficiency of the rejection, we submit, as noted above in the Interview Summary, the Declaration of Bruno Leuenberger, Ph.D., Under 37 CFR § 1.132 ("the Leuenberger Declaration"). Dr. Bruno Leuenberger is an inventor of the present application and a scientist at DSM who works in the area of formulation of nutritional and efficacious food compounds. His work has involved development of product forms of carotenoids, vitamins and other health-related ingredients for feed, food, and pharmaceuticals, with an emphasis on formulation of sparingly soluble actives and controlled release. Dr. Leuenberger has also investigated raw materials, especially protective colloids, for the development of new product forms. In addition, he has evaluated new formulation technologies, especially pertaining to micronization, emulsification and solidification. Dr. Leuenberger's Declaration evidences that the claimed powder compositions are not obvious over Auweter alone or in view of Stein.

For the Examiner's convenience, we note that claim 1 recites "[a] powder composition comprising at least one fat-soluble vitamin dispersed in a matrix consisting of an emulsion-forming composition selected from the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof, wherein the fat-soluble vitamin is present in the powder composition in the form of solid droplets having an average diameter of about 80 to about 120 nanometers (nm) and wherein the fat-soluble vitamin is present in the powder composition in the amount of from about 10% to about 30% by weight."

Dr. Leuenberger's Declaration indicates that the claimed powder composition achieves optical clarity. (Leuenberger Decl. ¶¶ 5 and 6, and citations therein to the specification; and ¶ 20.) Dr. Leuenberger also states that there is a direct relationship between the amount of light reflected from any droplets present and the degree of turbidity which is reported in units of NTU (Nephelometric Turbidity Unit). (Leuenberger Decl. ¶ 6 and citations therein to the specification; and ¶ 20.) Dr. Leuenberger further discloses that optical clarity (NTU) is a function of the droplet size of the claimed composition, as shown in Figure 2. (Leuenberger Decl. ¶ 6, and citations therein to the specification; and ¶ 20.)

In his Declaration, Dr. Leuenberger explains that the general relationship between turbidity of lipid vesicle suspensions and particle size is indicated, for example, in Pozharski *et al.*, Relationship Between Turbidity of Lipid Vesicle Suspensions and Particle Size, (2001) 291, 158-162 (received September 15, 2000) ("Pozharski"). (Leuenberger Decl. ¶ 21; see Exhibit B of the Leuenberger Decl.) Dr. Leuenberger points out that as can be seen in Figure 1 on page 159 of Pozharski, turbidity is very low for particles having smaller diameters. (Leuenberger Decl. ¶ 21.) Dr. Leuenberger describes that for particle diameters below 200, turbidity approaches zero. (Id.) Pozharski discloses that the "size-turbidity dependence [data, including data not shown, indicates] that such behavior is inherent in the properties of lipid vesicles as light scatters." (Page 159, lines 2-7.)

Although Pozharski published after the priority date of the present application, the document should be considered because it "[shows] a universal fact [and thus it] need not be available as prior art before applicant's filing date." Manual of

Patent Examining Procedure, Eighth Ed., Rev. 7, July 2008, § 2124 (p. 2100-58). The MPEP indicates that such universal facts may include, for example, "a scientific truism." (Id.) Pozharski provides information regarding scientific aspects of turbidity and particle size which are consistent with information disclosed in the specification, as noted above, for instance.

Dr. Leuenberger also states that at a particle size of about 200 nm, particles are at a transitional point between the invisible and visible ranges of the spectrum. (Leuenberger Decl. ¶ 22.) Dr. Leuenberger states that at decreasing particle sizes below 200 nm, particles enter a size range which is not visible to the eye. Dr. Leuenberger further states that particles having an average diameter in a range of from about 80 to about 120 nm are in the invisible size range. (Id.) Dr. Leuenberger states that based on the foregoing, he believes that these particles are small enough to allow sufficient transmission of light such that a clear liquid in which a powder composition having such particles is added appears as a transparent and/or translucent solution which is essentially free from turbidity. (Id.) And, Dr. Leuenberger states that the claimed average diameter particle size range of about 80 to about 120 nm of the fat soluble vitamin in the form of solid droplets is integral to the favorable aspects achieved with the claimed powder composition of optical clarity and a transparent and/or translucent solution upon addition to a clear liquid. (Id.) It is apparent from the Leuenberger Declaration as well as the specification that the properties of optical clarity and appearing transparent and/or translucent in solution upon addition to a clear liquid are advantageous properties that inherently result from the powder composition as claimed.

Dr. Leuenberger states that the physicochemical properties of carotenes such as β-carotene and fat-soluble vitamins such as α-tocopherol, for example, are known to differ markedly. (Leuenberger Decl., ¶ 23.) See, *e.g.*, selected portions of The Merck Index, Fourteenth Ed. 2006 ("The Merck Index"), attached as Exhibit D to the Leuenberger Declaration. As indicated in the entry for β-carotene in The Merck Index, β-carotene is "[p]ractically [insoluble] in water", and its melting point is 183°C. (Leuenberger Decl. ¶ 23; Exhibit D, page 1854, lines 15 and 19.) Thus, Dr. Leuenberger points out that β-carotene is an insoluble solid compound. (Leuenberger Decl. ¶ 23.) The use indicated is as a "[y]ellow coloring agent for foods." (Leuenberger Decl. ¶ 23; Exhibit D, page 1854, line 26.) The melting point of α-tocopherol, on the other hand, is 2.5-3.5° C. (Leuenberger Decl. ¶ 23; Exhibit D, page 9494, under the structure of α-tocopherol.) Thus, Dr. Leuenberger states that α-tocopherol is a liquid oil, and it is known to be light or amber yellow in color. (Leuenberger Decl. ¶ 23.) Dr. Leuenberger further states that the physicochemical properties of β-carotene and fat-soluble vitamins differ in significant ways that affect the relative goals in formulating. (Id.) Dr. Leuenberger discloses that in looking to formulate a liquid oil to achieve a powder composition having optical clarity, i.e., being essentially free from turbidity in solution, and resulting in a transparent and/or translucent solution in a clear liquid, one skilled in the art would not have looked to technologies for formulating a solid, insoluble, colored compound which are for preparing compositions having color effects. (Id.)

Dr. Leuenberger indicates that in view of his extensive knowledge in the field, it is his understanding that given the stated goal of each of Auweter and Stein of providing powder coloring compositions, colorant particles in the disclosed formulations

of these documents would have an average diameter range such that the particles would be visible to the eye. (Leuenberger Decl. ¶ 24.)

Dr. Leuenberger discloses that from his review of Auweter, it is his understanding that Auweter provides a β-carotene powder composition that renders β-carotene, which is otherwise insoluble, dispersible as fine particles in cold water. (Leuenberger Decl. ¶ 25.) It is also his understanding that the dispersion disclosed by Auweter is a solid in liquid dispersion stabilized with colloids. (Id.) Dr. Leuenberger states that in view of the foregoing and Auweter's disclosed particle size of about 200 nm, it is his understanding that the coldwater-dispersible powder composition, when added to a previously clear liquid, would produce a turbid and colored solution. (Id.) Dr. Leuenberger also states that this is consistent with Auweter's stated goal of a coldwater-dispersible powder composition that provides color effects. (Id.)

Dr. Leuenberger opines that the coldwater-dispersible composition of Auweter is significantly different from the presently claimed powder composition. (Leuenberger Decl. ¶ 26.) For example, Dr. Leuenberger states that Auweter's β-carotene powder composition provides fine particles of β-carotene which would disperse as solid particles in liquid, whereas the claimed powder composition provides solid droplets of a fat-soluble vitamin dispersed in a matrix consisting of an emulsion-forming composition selected from the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof. (Id.; and ¶ 7.) Dr. Leuenberger states that the claimed emulsion-forming composition has sufficient emulsifying properties in an oil-in-water context to emulsify the oil into a fine dispersion in an aqueous medium and forms a stable emulsion of the

claimed droplet size. (Id.) Dr. Leuenberger further states that whereas Auweter's β-carotene powder composition having particle sizes of about 200 nm would produce a turbid and colored solution, the claimed powder composition having solid droplets of fat soluble vitamin with an average diameter of about 80 to about 120 nm achieves optical clarity and a transparent and/or translucent solution upon addition to a clear liquid. (Leuenberger Decl. ¶ 26.)

Based on the foregoing, Dr. Leuenberger concludes that Auweter provides no motivation for one skilled in the art to achieve the claimed powder composition. (Leuenberger Decl. ¶ 27.) Dr. Leuenberger states that, in fact, the use of β-carotene in Auweter to provide color effects is antithetical to the claimed powder composition which achieves optical clarity and a transparent and/or translucent solution upon addition to a clear liquid. (Id.) Dr. Leuenberger further states that Auweter's disclosure of "precipitated active substance particles ... with a diameter of, typically, 200 nm", a particle size which would appear visible in an otherwise clear solution, also flies in the face of obtaining the claimed powder composition which comprises solid droplets of a fat-soluble vitamin having an average diameter of about 80 to about 120 nm, which droplets are not in the visible range. (Id.)

Furthermore, Dr. Leuenberger indicates that Auweter does not disclose a process using an emulsion-forming composition that has sufficient emulsifying properties in an oil in water context to form a stable emulsion of the claimed droplet size. (Leuenberger Decl. ¶ 28.) Dr. Leuenberger states that Auweter's process differs from the process used in making the claimed powder composition. (Id.) Dr. Leuenberger explains that Auweter discloses how to make a solid in liquid dispersion of

fine particles of β-carotene stabilized with colloids. (Id.) Furthermore, Dr. Leuenberger states that Auweter provides no guidance as to how the presently claimed composition could be produced. (Id.) For example, he states that Auweter's disclosure of the use of atmospheric or superatmospheric pressure, e.g., in the range of 20 to 80 bar, preferably 30 to 60 bar, to produce a cold-water dispersible powder, provides no indication to use a high-pressure homogenization process, as disclosed. (Id.) In this regard, the Examiner is referred to ¶ 8 of the Leuenberger Declaration and citations to the specification provided therein, regarding the process of the present invention which is used to achieve the claimed powder composition of all of the presently pending claims that are under examination.

Dr. Leuenberger also indicates that even if one were to consider using greater pressure, although Auweter provides no suggestion of this, the literature indicates that pressure is not a result-effective variable in relation to the diameter of particles in an emulsion. (Leuenberger Decl. ¶ 29.) For example, Dr. Leuenberger states that Desrumaux and Marcand investigated the effect of pressure on the emulsification of sunflower oil (20%) in water using an ultra-high-pressure homogenizer. Desrumaux, A. and Marcand, J., Formation of Sunflower Oil Emulsions Stabilized by Whey Proteins with High-Pressure Homogenization (up to 350 MPa); Effect of Pressure on Emulsion Characteristics, *Intl J. Food Science and Tech.* (2002) 37, 263-269 ("Desrumaux"). (Id.; Leuenberger Decl. Exhibit E.) Desrumaux discloses:

> Homogenization reduced the Sauter diameter appreciably, the reduction increasing with treatment pressure from 50 to 90 MPa (Fig. 4). This result agrees with the study of Robin *et al.* (1992), who observed a decrease in the droplet average size between 7.8 and 76.3 MPa. Above 90 MPa, the [droplet diameter] increased with pressure (Fig. 4) and

> then stabilized approaching 200 MPa. Robin *et al.* observed a similar plateau of the droplet size diameter, but between 60 and 76.3 MPa.... Above 200 MPa, the [droplet diameter] decreased and then increased again at around 250 MPa. However, there was a final decrease of [droplet diameter] above about 300 MPa." (Page 267.)

Robin *et al.*, Microfluidization of Dairy Model Emulsions. I. Preparation of Emulsions and Influence of Processing on the Size Distribution of Milk Fat Globules (1992) *Lait*, 72 511-550 ("Robin"), which is cited by Desrumaux, is also provided with the Leuenberger Declaration as Exhibit F.[1] Dr. Leuenberger states that the literature thus indicates that particle diameter has no consistent relation to pressure. (Leuenberger Decl. ¶ 29.)

In sum, Auweter discloses a different process, and provides no guidance as to the process used to produce the claimed powder composition. Moreover, the art provides no expectation of success in using a greater pressure parameter.

Regarding Stein, Dr. Leuenberger states that it is his understanding that the process of Stein is similar to the process of Auweter in achieving their mutual goal of preparing carotenoid powder compositions for use as colorants. (Leuenberger Decl. ¶ 30.) The principle difference between the processes, according to Dr. Leuenberger, is that Auweter discloses the use of a water-miscible organic solvent, whereas Stein discloses the use of a water immiscible organic solvent in the first step of forming a suspension of a carotenoid. (Id.) Dr. Leuenberger states that he is not aware of any reason why the very similar processes of Stein and Auweter would not achieve substantially the same results in terms of carotenoid particle size. (Id.) Moreover, he

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[1] Although Desrumaux published after the priority date of the present application, it should be considered because it "[shows] a universal fact [such as] a scientific truism". MPEP § 2124 (p. 2100-58). In addition, it is noted that Robin is prior to the present application. The disclosure of Desrumaux provides information that is consistent with Robin.

indicates that he would expect that the processes of Stein and Auweter would produce carotenoid particle sizes in a comparable range. (Id.)

In addition, Dr. Leuenberger indicates that he is familiar with the Stein Declaration. (Leuenberger Decl. ¶¶ 17 and 31-32.) Dr. Leuenberger refers to the Stein Declaration, as follows:

> 31. In the Stein Declaration, Mr. Hermann Stein declares that "[d]uring the research that led to the invention disclosed in Stein, my co-inventors and I, using the knowledge available at the time, attempted to produce the smallest possible particle size. (Paragraphs 6, lines 1-3.) Stein reproduced Example 5 of Stein, "with a view toward optimizing the process by producing the smallest particle size." (Paragraph 6, lines 3-4.) Example 5, which is found at Col. 6, paragraphs 54-58 of Stein, is also reprinted in paragraph 6 of the Stein Declaration.
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> 32. Stein declares that "[a]s Example 5 shows, at that time, at best we could produce particle sizes of about 196 nm. (Paragraph 7, lines 1-2.) Stein also declares that "[b]ased on my unique knowledge of the methods and compositions of Stein, and my long experience in the area of the production carbohydrate matrices, it is my opinion that one of skill in the art at the time of the above-captioned invention familiar with the disclosure of Stein could not have produced particles of the presently claimed size." (Paragraph 7, lines 2-6.) Stein further declares that "it is also my opinion that one could not have predicted that the process of the present invention would produce significantly smaller particle sizes than the methods of Stein." (Paragraph 8.)
>
> (Leuenberger Decl. ¶¶ 31-32.)

Dr. Leuenberger states that he agrees with H. Stein's analysis and conclusions. (Leuenberger Decl. ¶ 33.) Accordingly, in view of all of the foregoing, it is Dr. Leuenberger's opinion that one skilled in this art could not have predicted from Auweter alone or in view of Stein that the claimed powder composition could be

produced having a fat soluble vitamin in the form of solid droplets having an average diameter of about 80 to about 120 nm, and which achieves optical clarity and a transparent and/or translucent solution upon addition to a clear liquid. (Id.)

Consistent with Dr. Leuenberger's opinion, achieving a successful powder composition as presently claimed that has the inherent advantages of optical clarity and a transparent and/or translucent solution upon addition to a clear liquid could not have been predicted by one of skill in the art. Here, known options for preparing a powder composition as indicated by Auweter alone or in view of Stein, were not "finite, identified, and predictable", as in the facts presented in *KSR Int. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007). In *Abbott Labs. v. Sandoz, Inc.*, 89 USPQ 1161, 1171 (Fed. Cir. 2008), the Court of Appeals for the Federal Circuit indicated that the Supreme Court in *KSR* "did not create a presumption that all experimentation in fields where there is already a background of useful knowledge is 'obvious to try,' without considering the nature of the science or technology."

The Court of Appeals for the Federal Circuit has reaffirmed that "hindsight claims of obviousness" are improper. In distinguishing between fact patterns where a combination of known elements may or may not be proper, the Federal Circuit clearly articulated that simply varying all possible parameters until the claimed invention is arrived at in the absence of either an indication of which parameters to vary or an indication of which of many possible choices is likely to be successful is impermissible hindsight reconstruction. Indeed, the Federal Circuit concluded:

> Similarly, patents are not barred just because it was obvious "to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention

> or how to achieve it." *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989, 997 (Fed. Cir. 2009), *citing In re O'Farrell*, 853 F.2d 894, 903.

Moreover, as in the *Abbott* case, one skilled in the art would not have anticipated success in achieving the presently claimed powder composition, as "knowledge of the goal does not render its achievement obvious." *Abbott Labs. v. Sandoz, Inc.*, 89 USPQ at 1172 (affirming the district court's determination that Abbott is likely to prevail in its claim that the patent is valid, and upholding the grant of a preliminary injunction).

Clearly, the Examiner's rejection over Auweter alone or in view of Stein is based on impermissible hindsight reconstruction and is improper. Moreover, any modification of Auweter or combination of Auweter and Stein can not lead to the present claims.

In view of all of the foregoing, the rejection has been rendered moot. Reconsideration and withdrawal are respectfully requested.

B. <u>Claim 15: Auweter Alone or in View of Stein, and Further in View of Emodi</u>

Claim 15 was rejected under 35 U.S.C. § 103(a) as being obvious over Auweter alone or view of Stein as applied to claims 1, 3-14 and 17 above, and further in view of Emodi et al. US Patent No. 3,886,294 ("Emodi"). (Paper No. 20090330 at 4.)

Auweter and Stein are summarized above.

Emodi discloses "[l]iquid and powder carotenoid coloring compositions suitable for the preparation of optically clear, stable aqueous solutions, and the

preparation thereof..." (Abstract, lines 1-3.) Emodi also discloses that "[t]he composition [consists] of one or more carotenoid coloring substances, an antioxidant and an emulsifier ingredient comprising a polysorbate and a mixture of monoglycerides of low molecular weight saturated coconut fatty acids and up to two optional emulsifier components selected from the group consisting of a mixture of saturated fractions of coconut oil triglycerides and a polyoxyethylene (40) stearate wax." (Abstract, lines 3-11.) Emodi further discloses that "[t]he carotenoid coloring compositions, ... whether in the liquid or powder form, contain from about 0.1 to about 2.0 percent by weight, preferably from about 0.3 to about 1.0 percent by weight of the carotenoid coloring agent." (Col. 2, lines 13-17). Each of the powder composition examples, Examples 1, 2, and 4-7, includes either 0.3 percent, 0.5 percent, or 1 percent of a carotenoid compound. (Col. 4, line 50 to Col. 5, line 39, and Col. 6, line 1 to Col. 7, line 41.) The powder form of Emodi's compositions is also said to include "a water-soluble carrier composition which comprises a sugar, e.g., sucrose, fructose, lactose, invert sugar and the like and a water-soluble colloid-former such as, for example, hydrolyzed gelatin, low or high bloom gelatin and mixtures of hydrolyzed cereal solids and sugar..." (Col. 2, lines 25-33.) In addition, Emodi discloses that "aqueous solutions of the compositions ... formed from the various liquids and powders can be passed through a filter which will retain particles larger than 0.22 micron without loss of color." (Col. 4, lines 30-34.)

Emodi also discloses that "the powdered carotenoid coloring compositions of the invention are prepared by initially forming a supersaturated carotenoid liquid [which is] prepared by heating the combined components of the emulsifier ingredient and the preservative and dissolving the carotenoid coloring agent therein. A

temperature of from about 80° to about 140°C. preferably from about 100° to about 120°C. is contemplated." (Col. 4, lines 6-9 and Col. 3, line 63 to Col. 4, line 1.) Emodi further discloses that the supersaturated carotenoid liquid "while still at the formation temperature, i.e. preferably at a temperature of from about 100° to 120°C., [is added] to a previously formed aqueous solution containing the carrier composition, i.e. the soluble colloid-forming component, sugar and preservatives. The combined solutions are thereafter spray dried utilizing conventional spray drying equipment. The resultant spray dried powder is composed of submicroscopic droplets of a solution of a carotenoid coloring material in emulsifier ingredient encased in a water soluble colloidal film." (Col. 4, lines 9-19.) Example 1 of Emodi is said to provide a powder preparation containing 0.5 percent by weight β-apo-8'-carotenal. The spray dried powder is disclosed as "having a moisture content of less than 2 percent by weight." (Col. 4, line 50 to Col. 5, line 12.)

In making the rejection, the Examiner acknowledged that "Auweter and [Stein] fail to teach the claimed moisture content." (Paper No. 20090330 at 4.)

The Examiner asserted, however, that "Emodi ... teaches a powder preparation of carotenoids wherein the powder is prepared by mixing fish gelatin with carotenoids [sic] crystals and spray drying the resultant solution to a [sic] form stable powder of moisture content less than 2% (example 1 in col. 4)." (Id.)

The Examiner concluded that "it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the powders of Auweter or Auweter and [Stein] by spray drying where the final moisture content is less

than 2% because Emodi suggests stability of the powders. A skilled artisan would have expected the powders of Auweter to be stable." (Id.)

The arguments presented above in response to the rejection over Auweter alone or in view of Stein are incorporated here. Because the rejection above over Auweter alone or in view of Stein as applied to claims 1, 3-14 and 17 has been rendered moot, for this reason alone, the present rejection as applied to claim 15 cannot stand.

In addition, the deficiencies in the Examiner's citation of Auweter alone or in view of Stein are not remedied by the Examiner's additional citation of Emodi.

In the Leuenberger Declaration, Dr. Leuenberger indicates that in view of his extensive knowledge in the field, it is his understanding that given the stated goal of each of Auweter, Stein, and Emodi of providing powder coloring compositions, colorant particles in the disclosed formulations of these documents would have an average diameter range such that the particles would be visible to the eye. (Leuenberger Decl. ¶ 24.)

With regard to Emodi, Dr. Leuenberger states that Emodi's disclosure of powder carotenoid coloring compositions having only about 0.1 to about 2.0 percent by weight, preferably from about 0.3 to about 1.0 percent by weight of a carotenoid coloring agent, in addition to the required emulsifiers, does not suggest the claimed powder composition having a fat-soluble vitamin in the amount from 10% to about 30% by weight of the composition. (Leuenberger Decl. ¶ 34.) Dr. Leuenberger also states that in view of Emodi, one skilled in the art would have been led toward low

percentages of active substance in combination with emulsifiers, rather than to the claimed powder composition. (Id.)

To modify Emodi as suggested by the Examiner would be to alter Emodi's process/composition in a manner not intended and, in fact, contrary to its teaching. But, as is well settled, to do what the prior art teaches against is the very antithesis of obviousness. See, *e.g.*, *In re Rosenberger*, 156 USPQ 24, 26, (CCPA 1968) and *In re Buehler*, 185 USPQ 781, 787 (CCPA 1975). For this reason alone the rejection should be withdrawn.

Furthermore, Dr. Leuenberger states that it is his understanding that Emodi's disclosure that various liquids and powders can be passed through a filter which retains particles larger than 0.22 micron without loss of color indicates that Emodi's powder contains particles larger than 0.22 micron, and that colored particles retained in the filtered solution have a particle size in the visible range. (Id.) (Leuenberger Decl. ¶ 34.)

Dr. Leuenberger opines that in view of the foregoing, one skilled in the art could not have predicted from Auweter alone or in view of Stein and Emodi that the claimed powder composition could be produced having a fat soluble vitamin in the form of solid droplets having an average diameter of about 80 to about 120 nm which is present in the powder composition in the amount of from about 10% to about 30% by weight, and having from about 60 to 85% by weight of a matrix component based on the total weight of all the components present in the composition, wherein the composition has a moisture content of about 1-4% by weight, and achieves optical

clarity and a transparent and/or translucent solution upon addition to a clear liquid. (Leuenberger Decl. ¶ 34.)

As is noted above, hindsight claims of obviousness are improper. *See e.g., Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d at 997. Clearly, the Examiner's rejection is based on impermissible hindsight reconstruction and is improper. Moreover, any such combination can not lead to the present claim.

In view of all of the foregoing, the rejection has been rendered moot. Reconsideration and withdrawal are respectfully requested.

Double Patenting Rejection

The double patenting rejection has been maintained. (Paper No. 20090330 at 5.) Accordingly, we understand that the rejection that the Examiner has maintained is the rejection of claims 1, 3-15 and 17 under the judicially created doctrine of obviousness-type double patenting over claims 1-20 of Chen et al., US Patent No. 6,162,474 ("Chen").[2] (Paper No. 20080622 at 6.)

As noted on the record, until allowability is determined, requiring a Terminal Disclaimer is premature. MPEP § 1490. Upon notification of allowability of the application but for the double patenting rejection, a Terminal Disclaimer may be submitted.

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[2] If this is not correct, we ask the Examiner to so indicate.

For the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on December 2, 2009.

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Respectfully submitted,

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